

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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PATRICK HUGHES and NAFISE NINA  
HODJAT, individually and on behalf of all others  
similarly situated,

Plaintiffs,

—against—

THE ESTER C COMPANY, NBTY, INC., and  
NATURESMART, LLC,

Defendants.

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**MEMORANDUM &**  
**ORDER**

12-CV-0041 (PKC) (GRB)

PAMELA K. CHEN, United States District Judge:

Plaintiffs Patrick Hughes and Nafise Nina Hodjat (together, “Plaintiffs”) initiated this putative consumer class action on behalf of themselves and proposed classes of individuals who bought vitamin C dietary supplements sold by The Ester C Company, NBTY, Inc., and Naturesmart LLC (collectively, “Defendants”) under the name “Ester-C.” Plaintiffs assert claims under California and Missouri statutes and New York common law, alleging that Defendants deceptively packaged and marketed Ester-C products through false or misleading representations that Ester-C products are a form of immune system support that would decrease the likelihood of getting or remaining ill, and that Ester-C is a superior source of vitamin C. Defendants have filed a motion for partial summary judgment arguing that Plaintiffs’ state law claims regarding Ester-C’s “Immune Support” statements are preempted by federal law. (Dkt. 66.)<sup>1</sup> For the reasons set forth below, Defendants’ motion is denied.

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<sup>1</sup> Also pending before the Court is Plaintiffs’ request to certify a nationwide class of consumers, as well as classes of consumers in Missouri and California. (See Dkt. 82.) That motion will be addressed in a separate memorandum and order.

## ***BACKGROUND***

The Court presumes the parties' familiarity with the factual allegations in the Amended Complaint, which are also detailed in the Court's prior order denying Defendants' motion to dismiss. *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439 (E.D.N.Y. 2013).<sup>2</sup>

Briefly, the Ester-C dietary supplements at issue in this action contain high doses of vitamin C in the form of calcium ascorbate. (Dkt 70 ("Def. St.") ¶ 1.) According to Plaintiffs, misrepresentations in Ester-C's packaging and marketing create a reasonable expectation with purchasers that Ester-C provides a form of immune system defense that protects users from illnesses, and decreases one's likelihood of getting or remaining ill. (Dkt. 13 ("Am. Compl.") ¶¶ 2, 25; Dkt. 71 ("Pl. Mem.") at 2.) There is no dispute that the label for each of Ester-C's products prominently features an emblem with the words "Immune Support," including variants such as "immune system support." (Am. Compl. ¶ 17; Dkt. 67 ("Def. Mem.") at 2–3). Equally undisputed is that labels on Ester-C products do not expressly mention the words "cold," "flu" or other diseases. (Def. Mem. at 4; *see* Pl. Mem. 2–3.)

Plaintiffs allege that Ester-C product labels also feature false or misleading statements that: (1) Ester-C "provides your body with the immune and antioxidant support it needs to help keep you healthy and strong during times of seasonal change and the stresses of daily living"; (2) supports "Antioxidant Health"; and (3) provides "24 Hour Immune Support." (Am. Compl. ¶¶ 2, 17.) Plaintiffs' Amended Complaint further alleges that Defendants' marketing and advertising underscore these misleading representations. (*Id.* ¶¶ 19–24.) The Ester-C website, for instance, recommends taking Ester-C as one way to help stay healthy during winter months.

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<sup>2</sup> The case was assigned to the Honorable Joseph F. Bianco at that time.

(*Id.* ¶ 20.) In addition, Plaintiffs allege that Defendants falsely portray Ester-C as the “Better Vitamin C.” (*Id.* ¶ 17.)

In their summary judgment motion, Defendants argue that Plaintiffs’ challenge to Ester-C’s “immune support” statement is preempted by federal law because Congress and the Food and Drug Administration (“FDA”) have directly addressed which statements manufacturers may, and may not, make in nutritional supplement labeling. (Def. Mem. at 1.) Specifically, Defendants contend that “as a matter of federal law, the statement ‘immune support’ *does not imply* disease treatment or prevention.” (*Id.* (emphasis in original).) Indeed, Defendants’ motion “is strictly limited to the statement of ‘Immune Support’[,]” and “does not seek to preclude Plaintiffs’ attack on any other statement on Ester-C packaging.” (Dkt. 72 (“Reply”) at 2; *see* Def. Mem. at 3 n.2 (noting that comparative claims that Ester-C is “better” are not at issue).)

## ***DISCUSSION***

### **I. Legal Standard**

Summary judgment is proper only when, construing the evidence in the light most favorable to the non-movant, “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FRCP 56(a); *see also Redd v. N.Y. Div. of Parole*, 678 F.3d 166, 174 (2d Cir. 2012). A dispute is “genuine” when “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material when it “might affect the outcome of the suit under the governing law.” *Id.* Because Plaintiffs, as the non-moving party, have the “burden of proof at trial” on their claims, Defendants’ ability to satisfy this standard as to any “essential element” of a claim “necessarily renders all other facts immaterial,” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986), and entitles Defendants to summary judgment.

In determining whether there are genuine disputes of material fact, the court must “resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought.” *Terry v. Ashcroft*, 336 F.3d 128, 137 (2d Cir.2003) (citation and quotation omitted). The non-moving party cannot avoid summary judgment simply by relying “on conclusory allegations or unsubstantiated speculation.” *Jeffreys v. City of New York*, 426 F.3d 549, 554 (2d Cir. 2005) (quotations and citations omitted). That party must offer “some hard evidence showing that its version of the events is not wholly fanciful.” *Miner v. Clinton Cnty., New York*, 541 F.3d 464, 471 (2d Cir. 2008) (quotations and citation omitted).

## **II. Federal Regulatory Context**

The federal Food, Drug, and Cosmetic Act (the “FDCA”), enacted in 1938, “empowers the [FDA] to (a) protect the public health by ensuring that ‘foods are safe, wholesome, sanitary, and properly labeled,’ 21 U.S.C. § 393(b)(2)(A); (b) promulgate regulations pursuant to this authority; and (c) enforce its regulations through administrative proceedings[,] [s]ee 21 C.F.R. § 7.1 *et seq.*” *Jovel v. i-Health, Inc.*, 12 CV 5614, 2013 WL 5437065, at \*3 (E.D.N.Y. Sept. 27, 2013). In 1990, Congress amended the FDCA by enacting the Nutrition Labeling and Education Act (the “NLEA”), codified, as amended, at 21 U.S.C. §§ 301, 321, 337, 343, 371. “The NLEA was passed to ‘clarify and to strengthen the [FDA’s] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.’” *Nutritional Health Alliance v. Shalala*, 144 F.3d 220 (2d Cir. 1998) (citing H.R. Rep. No. 101-538, at 7 (1990)).<sup>3</sup>

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<sup>3</sup> Enforcement of the FDCA is exclusively the responsibility of the FDA. The FDCA does not create a private right of action. Hence, individuals seeking to bring actions about false or misleading drug labels must do so under state law. *See Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 810 (1986).

Defendants' motion focuses on a section of the NLEA "establish[ing] standards with respect to dietary supplements" that was added by Congress in 1994 through the passage of the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325; *see Jovel*, 2013 WL 5437065, at \*4 (DSHEA "created a new regime for the FDA's regulation of dietary supplements"). The term dietary supplements are defined in the DHSEA to include vitamins. 21 U.S.C. § 321(ff).<sup>4</sup> The DSHEA allows dietary supplement labeling to include, among other types of statements, a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" ("structure/function claims"). *Id.* at § 343(r)(6)(A).<sup>5</sup> Such structure/function claims do not require FDA

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<sup>4</sup> Under the DSHEA, "dietary supplements," which are defined to include vitamins, minerals, amino acids and herbs, are a "food" and are not to be classified as a "drug" under section 321(g)(1). *See* 21 U.S.C. § 321(ff).

<sup>5</sup> Section 343(r)(6) provides, in relevant part:

[A] statement for a dietary supplement may be made if--

- (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, *describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans*, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
- (B) the manufacturer of the dietary supplement *has substantiation that such statement is truthful and not misleading*, and
- (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of

pre-approval. Instead, companies that make structure/function claims must provide notice to the FDA within thirty days of first use of the claim, have “substantiation that such statement is truthful and not misleading,” and include a disclaimer on the label stating that the FDA has not evaluated the claim and that the product is not intended to “diagnose, treat, cure or prevent any disease.” *Id.* at § 343(r)(6)(B)–(C); *see* 21 C.F.R. § 101.93. Section 343(r)(6) expressly prohibits claims that dietary supplements can “diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases” (“disease claim”). 21 U.S.C. § 343(r)(6); *see id.* at §§ 343(r)(1)(B) and (r)(5)(D) (requiring prior authorization to make claims on a dietary supplement label that “characterize the relationship of any nutrient . . . to a disease or a health-related condition”). Additionally, a dietary supplement may be misbranded where “its labeling is false or misleading in any particular.” *Id.* at § 343(a)(1).

In 2000, the FDA promulgated a regulation regarding the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. 65 Fed. Reg. 1000–01; 21 CFR § 101.93. The regulation established criteria for determining when a dietary supplement claim is an acceptable structure/function claim or a prohibited disease claim. 65 Fed. Reg. 1000–01 at 10001, I.B; *see* 21 C.F.R. § 101.93(f) (“[p]ermitted structure/function statements”) and § 101.93(g) (listing criteria for “disease claims”). The FDA warned that the rule is not “intended to establish whether any particular structure/function claim is appropriate for any specific product,” and that “an otherwise acceptable structure/function

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this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

21 U.S.C. § 343(r)(6) (emphasis added).

claim might nevertheless be false or misleading for other reasons.” 65 Fed. Reg. 1000–01 at 10001.

In proposing and responding to public comment on the criteria for disease claims, the FDA cited examples of disease claims, such as “supports the body’s antiviral capabilities” or “supports the body’s ability to resist infection.” *Id.* at 1028. By contrast, the FDA explained that “[a] more general reference to an effect on a body system that did not imply prevention or treatment of a disease state would not [] constitute[] a disease claim under this criterion[,]” and cited the claim that a product “supports the immune system” as a structure/function claim. *Id.* at 1028–29. The FDA explained that the distinction “is one of specificity.” *Id.* at 1029.

A statement of support for the immune system, *by itself*, conveys no specific reference to disease treatment or prevention. The claim that vitamin A is necessary to maintaining a healthy immune response does not imply that a specific disease or class of diseases will be prevented. In contrast, a claim that a product “supports the body’s antiviral capabilities” represents a claim of treatment or prevention of a specific class of diseases, those caused by viruses (e.g., colds, hepatitis, or HIV infection).

*Id.* (emphasis added).

### **III. Federal Preemption of State Law Claims**

Under the Supremacy Clause of the United States Constitution, “state laws that conflict with federal law are without effect” and are preempted. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (citation and internal quotation marks omitted); U.S. Const., art. VI, cl. 2. Congress’s purpose in enacting the law at issue “is the ultimate touchstone in every pre-emption case.” *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citations and internal quotation marks omitted). In addressing preemption questions, courts “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *United States v. Locke*, 529 U.S. 89, 107 (2000) (quoting *Rice*

*v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The presumption against preemption applies with particular force “where federal law is said to bar state action in fields of traditional state regulation.” *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995); *see Altria Grp.*, 555 U.S. at 77. Given the traditional “primacy of state regulation of matters of health and safety,” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see Travelers*, 514 U.S. at 654–55, courts assume “that state and local regulation related to [those] matters . . . can normally coexist with federal regulations.” *Hillsborough Cnty. v. Automated Med. Labs., Inc.* 471 U.S. 707, 718 (1985). As a result, where the text of a preemption clause is ambiguous or open to more than one plausible reading, courts “have a duty to accept the reading that disfavors pre-emption.” *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005); *see Medtronic*, 518 U.S. at 485 (where Congress enacts an express preemption clause, the presumption requires courts to read the clause narrowly) (citing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992)).

The NLEA added a preemption provision to the FDCA. It states, in pertinent part:

(a) Except as provided in subsection (b) of this section [*i.e.*, petition to the Secretary for exemption], no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

...

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title [*i.e.*, nutrition level and health claims], made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title . . . .

21 U.S.C. § 343–1(a)(5). The Second Circuit noted that “the NLEA is clear on preemption, stating that it shall not be construed to preempt any other provision of State law, unless such provision is *expressly preempted* under [21 U.S.C. § 343–1(a)] of the [FDCA].” *N.Y. State Restaurant Ass’n v. N.Y. City Bd. of Health*, 556 F.3d 114, 123 (2d Cir. 2009) (citation omitted)

(emphasis and alterations in original). This provision “has been repeatedly interpreted *not* to preempt requirements imposed by state law that effectively parallel or mirror the relevant sections of the NLEA.” *Jovel*, 2013 WL 5437065, at \*3 (citing cases) (emphasis added). “Thus, the NLEA contemplates state enactment and enforcement of labeling requirements as long as they are identical to or parallel NLEA requirements.” *Id.*; *see Ackerman v. Coca-Cola Co.*, 09 CV 0395, 2010 WL 2925955, at \*6 (E.D.N.Y. July 21, 2010) (claims under state laws that parallel the FDCA’s requirements are not preempted). Additionally, a plaintiff’s claims “may avoid preemption . . . even if they seek to impose additional ‘requirements’ on a defendant, as long as any such requirement is not ‘respecting any claim of the type described in Section 343(r)(1).’” *Ackerman*, 2010 WL 2925955, at \*7 (quoting 21 U.S.C. § 343–1(a)(5)).

Defendants move for partial summary judgment on the ground that the labeling statement “immune support” is expressly authorized by federal law, and therefore Plaintiffs’ challenge under state law to statements of “immune support” is preempted. (Def. Mem. at 1, 6; Reply at 1 (Defendants “seek[] a ruling that Plaintiff s’ challenge to the ‘Immune Support’ statement is preempted”).) Plaintiffs have opposed the motion, contending that their state law claims are not preempted because they are based on alleged false or misleading health claims on Defendants’ packaging that are not permitted by federal law. Plaintiffs further assert that the state laws at issue impose no requirements beyond those imposed by federal law. (Pl. Mem. at 1.)

Were “Immune Support” the sole claim being challenged by Plaintiffs on Ester–C’s packaging, Defendants might be correct. As discussed above, the FDA considers a claim of “immune support,” standing alone, to be an archetypal structure/function claim. *See* 65 Fed. Reg. 1000–01 at 1028–29. However, Defendants’ motion artificially narrows the nature of Plaintiffs’ claims, which do not hinge exclusively on Ester–C’s “Immune Support” statements.

Rather, Plaintiffs assert that Ester-C’s “immune support” statements, in combination with the disease prevention/treatment statements that appear in the packaging and marketing of Ester-C products, constitute misleading representations as to Ester-C’s health benefits. (See Pl. Mem. at 9.)<sup>6</sup> Far from relying on an argument that Defendants’ claim of “Immune Support,” in itself, is misleading, Plaintiffs’ Amended Complaint specifically identifies as misleading several other statements in Ester-C labels and marketing. For example, the Amended Complaint alleges that Ester-C labels feature the statement that “Ester C provides your body with the immune and antioxidant support it needs *to help keep you healthy and strong during times of seasonal change and the stresses of daily living.*” (Am. Compl. ¶ 17 (emphasis added).)<sup>7</sup>

In effect, Defendants are asking the Court to separately analyze the “Immune Support” statements, divorced from the other statements that accompany them, as well as the context in which they appear in Ester-C’s packaging and marketing. This approach defies both common sense and reality, and is contrary to the FDA’s guidance that the specificity of a statement may nudge the claim outside the realm of a mere structure/function claim. *See* 65 Fed. Reg. 1000–01 at 1029 (emphasis added); see id (“The distinction . . . is one of specificity.”)

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<sup>6</sup> Significantly, none of Judge Bianco’s findings in denying Defendants’ prior motion to dismiss rested solely on allegations that a statement of “Immune Support” by itself was misleading; instead, Judge Bianco carefully considered Plaintiffs’ pleadings and found that their claims were sufficiently supported by allegations regarding specific representations on Ester-C’s packaging, labeling, and marketing. *See Hughes*, 930 F. Supp. 2d at 465-76.

<sup>7</sup> The fact that Plaintiffs’ Amended Complaint premises liability, in part, on Ester-C’s “immune support” statements, or that, in their prayer for relief, Plaintiffs seek to prohibit Defendants from using “Immune Support” language in their labels and marketing of Ester-C (*see* Def. Mem. at 4 (citing Am. Compl. ¶¶ 56, 62, 80, 84, Prayer for Relief ¶ D)), is insufficient to alter this conclusion. Construing the claims favorably towards the Plaintiffs as the non-moving party, the Court interprets them as shorthand for the broader disease claims that Plaintiffs allege are misleading. (*See, e.g.*, Am. Compl. ¶¶ 56, 62 (“help[s] prevent a user from getting or remaining sick”).

Defendant's proposed approach is also inconsistent with the court's analysis in *Gallagher v. Bayer AG*, 14 CV 4601, 2015 U.S. Dist. LEXIS 29326 (N.D. Cal. Mar. 10 2015), cited by Defendant in a supplemental submission dated May 20, 2015 (Dkt. 90). In *Gallagher*, the court found that a statement that One A Day multivitamins "support immunity" is a permissible structure/function claim under federal law, and that the plaintiffs' claims based on that statement were preempted. *Id.* at \*22. Unlike Plaintiffs here, however, the *Gallagher* plaintiffs challenged the immune support statement on its own, without reference to other statements on the multivitamin packaging or marketing. *Id.* at \*21. More importantly, the court in *Gallagher* recognized that the immune support language may be actionable if additional language "on the packaging, websites, or in advertisements of the [multivitamin] [] would take the 'supports immunity' language and move it towards a disease claim." *Id.* The court thus dismissed the claim with leave to amend "to plead facts showing th[e] ['support immunity'] [s]tatement has been linked—by virtue of specifically identified packaging or marketing—to treatment or prevention of disease." *Id.* at \*22. Here, as detailed above, Plaintiffs have put forth specific statements on Ester-C product labels and marketing that a jury could find links Defendants' immune support statements to the prevention and treatment of illness.

The decision in *Ackerman v. Coca-Cola Company*, 09 CV 0395, 2010 WL 2925955 (E.D.N.Y. July 21, 2010), although addressing a different set of FDA regulations, confirms the use of this contextual approach. *Ackerman* involved a challenge to statements on "vitaminwater"<sup>8</sup> labels that portrayed the product as "healthy" or implied that the product helps

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<sup>8</sup> In the decision, the Honorable John Gleeson adopted the defendants' lower case spelling of the product, which was marketed as "VitaminWater." *Id.* at \*1 n.2.

consumers maintain healthy dietary practices. *Id.* at \*5–6, 9.<sup>9</sup> FDA regulations restrict the assertion of health claims or “nutrient-content claims” that suggest a food may help consumers maintain healthy dietary practices. *See* 21 C.F.R. §§ 101.14(e) (6); 101.65(d)(2). To determine whether statements on the vitaminwater labels were impermissible “nutrient-content claims,” the court in *Ackerman* looked to the context in which the term “healthy” was used on the labels, and found that descriptions of the product, other statements on the label, and flavor names associated with specific purported health benefits “collectively” suggested that the product may assist consumers in maintaining healthy dietary practices. *Id.* at \*10–11.<sup>10</sup> Plaintiffs’ claims in this case are analogous in that they contend that the Ester-C “immune support” statements, together with other statements made in the product labeling and marketing, imply a disease claim that Ester-C protects users from illnesses. Given the broader scope of Plaintiffs’ claims, the Court cannot, as Defendants urge, consider the permissibility of immune support statements in isolation.<sup>11</sup>

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<sup>9</sup> For instance, the label on the vitaminwater “defense” flavor stated that the “the trick is to stay *healthy* . . . [and that the product’s] combination of zinc and fortifying vitamins can help out with that and keep you *healthy* as a horse.” *Id.* at \*10 (emphasis in *Ackerman*). A statement on the vitaminwater “B–Relaxed” flavor claimed that the combination of nutrients in the product “can help bring about a *healthy* state of physical and mental being.” *Id.* (emphasis in *Ackerman*).

<sup>10</sup> Addressing the plaintiffs’ other claim that vitaminwater’s health statements were also misleading because they distracted consumers from the product’s high sugar content, Judge Gleeson recognized that this claim was preempted by the FDA’s decision that sugar content alone does not prohibit a health claim or nutrition-content claim. *Id.* at \*8 (“any claim under state law solely premised on the notion that vitaminwater’s high sugar content made its health or implied nutrient content claims misleading [was] preempted by the FDA’s express decision to not recognize sugar as a disqualifying nutrient”).

<sup>11</sup> The Court considers Defendants’ arguments more appropriate for a *motion in limine*. Should this case proceed to trial, the Court would instruct the jury that a statement that Ester-C products provide “immune support” standing alone is not a disease claim as a matter of federal law. The Court would also instruct the jury that statements that Ester-C provides “Antioxidant Health” and “24 Hour Immune Support” likewise are not by themselves disease claims. Rather, the jury

Plaintiffs have offered sufficient evidence to support its claim that “Immune Support” statements on Ester-C packaging, used in the context of other statements—*e.g.*, “Ester C provides your body with the immune and antioxidant support it needs to help keep you healthy and strong during times of seasonal change and the stresses of daily living” (Am. Compl. ¶¶ 2, 17)—are not merely structure/function claims, but, in fact, health or disease claims that require prior FDA authorization. A reasonable jury could view these supplementary statements as adding specificity to Defendants’ immune support claims that brings them closer to disease claims that require prior authorization from the FDA, such as “supports the body’s antiviral capabilities” or “supports the body’s ability to resist infection.” 65 Fed. Reg. 1000–01 at 1029 (examples of disease claims cited by the FDA). Plaintiffs have, therefore, created a factual issue as to whether Defendants violated DSHEA and FDA regulations by making disease claims about Ester-C without prior authorization, and whether these statements are misleading, in violation of the FDCA’s prohibition on misbranding. *See* 21 U.S.C. § 343(a)(1). Because Plaintiffs’ claims under state law seek to impose requirements that are identical to those required by federal law, they are not preempted by federal law under either an express or implied preemption theory. *See Ackerman*, 2010 WL 2925955, at \*7 & \*13 (violations of FDCA and FDA regulations may be a basis for state law liability that are not preempted).<sup>12</sup>

Finally, the Court observes that Plaintiffs’ claims that Defendants misrepresented the efficacy of their product are traditional claims of consumer misrepresentation. *Jovel*, 2013 WL

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would be instructed that these statements must be considered in context of other claims made on Ester-C’s labeling and marketing.

<sup>12</sup> Plaintiffs also argue that the Defendants’ motion should be denied because their “immune support” statement fails to meet the regulatory requirements for a structure/function claim. (Pl. Mem. at 7.) Given the Court’s denial of Defendants’ motion, the Court need not, and declines to, address this alternate argument.

5437065, at \*5. “The FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles. The FDCA is not focused on the truth or falsity of advertising claims, but is directed to protecting the public by ensuring that drugs sold in the marketplace are safe, effective and not misbranded . . .” *Id.* at \*6 (quoting *Mut. Pharm. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (internal marks omitted)). In *Jovel*, the court held that although statements that are a part of a products’ labeling “may touch on an area regulated by the FDA, consumer protection claims founded on their falsity are not preempted.” *Id.* at \*5 (claim under state law that labels falsely stated that dietary supplement at issue supported brain development and function was not preempted). As in *Jovel*, Plaintiffs’ claims in this action likewise “do not require reference to FDA definitions, and the misleading nature of the statement[s] can be verified without relying on any special expertise of the FDA.” *See id.* Accordingly, the Court concludes that Plaintiffs’ claims that Defendants falsely or misleadingly marketed Ester-C products are not preempted.

### ***CONCLUSION***

For the reasons set forth above, Defendants’ motion for partial summary judgment is denied.

SO ORDERED:

/s/ Pamela K. Chen  
PAMELA K. CHEN  
United States District Judge

Dated: March 27, 2015  
Brooklyn, New York